IN THE SUPREME COURT OF THE STATE OF MONTANA
Case No. DA 10-0029

PEGGY STEVENS,
Plaintiff/Appellee.

vs.

NOVARTIS PHARMACEUTICALS CORPORATION,
Defendant/Appellant,

APPELLANT'S OPENING BRIEF

ON APPEAL FROM THE FOURTH JUDICIAL DISTRICT COURT
MISSOULA COUNTY, THE HONORABLE JOHN LARSON PRESIDING

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Filed: _____, 2010
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Statement of the Issues

1. In January 2008, Peggy Stevens filed suit against her oncologist, Dr. Schmidt, for failing to warn her of the risks of the drug Zometa®. Later – and after the statutory tort limitations period from the date of her injury – she amended her lawsuit to assert an identical claim against NPC. Montana's fictitious name statute permits amendment of a complaint when the plaintiff "[did] not know the name of the defendant at the time the original complaint was filed." Stevens admits that she knew the identity of NPC long before filing the original complaint. Is Stevens' claim against NPC barred by the statute of limitations?

2. Montana follows the learned intermediary doctrine, which provides that a drug manufacturer's duty to warn extends only to the prescribing physician. Over NPC's objection, and based on a Restatement of Torts (Third) section that has never been adopted by Montana or any other jurisdiction, the trial court instructed the jury that NPC's duty extended to other treating healthcare providers. In closing argument, Stevens' counsel urged the jury to find NPC liable for failing to warn providers other than the prescribing physician. Was the instruction erroneous?

3. Stevens' original complaint against Dr. Schmidt, her amended complaint, her expert disclosures, and her discovery responses, all state facts inconsistent with NPC's liability for failure to warn, such as the fact that Dr.

Schmidt was actually aware of the relevant risks of Zometa® at a time when a warning to Stevens would have prevented her injury. Stevens later settled with Dr. Schmidt. The trial court prevented NPC from cross-examining Stevens with this evidence or even from making the jury aware of the fact that Stevens had sued Dr. Schmidt. Was the exclusion of this evidence erroneous?

4. Dr. Schmidt was dismissed from the case on July 8, 2009, following a settlement, and Stevens responded to NPC's discovery request seeking information about the settlement on July 23, refusing to disclose anything. Twelve days later, NPC moved to amend its answer to add an apportionment defense. The trial court refused to permit NPC to amend its complaint on the ground that NPC did not act with "reasonable promptness." Was the trial court's refusal to permit amendment erroneous in light of the standard that leave to amend "shall be freely given when justice so requires"?

5. Stevens had dental surgery due to a broken tooth while she was on Zometa®. Her theory of causation was that the surgery triggered an adverse reaction to Zometa®, and that had she been warned, she would not have had the surgery. The uncontradicted evidence at trial established that Stevens had no choice about having some form of dental surgery to repair the broken tooth. Stevens offered no evidence that she had any surgical alternative that would have been less likely to trigger an adverse reaction to Zometa®. Did Stevens' failure to

establish that an adequate warning would have prevented her injury require entry of judgment for NPC?

6. Stevens brought a Montana Medical-Legal Panel proceeding against her oral and maxillofacial surgeon, Dr. Morris, for failing to warn her of the risks of dental surgery while on Zometa®. Dr. Morris stated in his answer that the dental surgery that Stevens had due to her broken tooth was the only realistic treatment option. When Dr. Morris contradicted this statement at trial by saying that there were other appropriate treatment options, NPC was prevented from impeaching him with his answer before the MMLP. Was the exclusion of Dr. Morris' statement erroneous?

7. Changes to pharmaceutical package inserts postdating the event that allegedly caused a plaintiff's injuries are subsequent remedial measures that are inadmissible under Montana Rule of Evidence 407. Joni Landes, a nurse employee of Dr. Schmidt's oncology practice, was permitted to testify at trial to a change to NPC's package insert for Zometa® that postdated the surgery that Stevens claims caused her injury. Was the admission of the Landes testimony erroneous?

Statement of the Case

Plaintiff Peggy Stevens sued defendant Novartis Pharmaceuticals Corporation ("NPC") for failing to warn that its drug Zometa® allegedly could cause a medical condition called osteonecrosis of the jaw ("ONJ") in patients who had dental surgery while taking the drug. The trial court denied NPC's pretrial motions for summary judgment, its motion to amend to state an apportionment defense after the original defendants settled, and its motions at trial for judgment as a matter of law. The jury entered a verdict for Stevens, awarding compensatory damages. The trial court denied NPC's post-trial motions for judgment as a matter of law and for a new trial.

Statement of Facts

1. Zometa® and Peggy Stevens' medical history.

Zometa® is an FDA-approved intravenous drug administered to patients who have certain cancers that have metastasized to bone. Patients with such cancers are at an increased risk of potentially life-threatening skeletal-related events such as fractures. Zometa® substantially reduces the risk of such injuries.

Peggy Stevens ("Stevens") was diagnosed with follicular lymphoma, a type of cancer, in October 2000 by Dr. Judy Schmidt, an oncologist. After finding metastatic cancer lesions on Stevens' spine and ribs, Dr. Schmidt prescribed Zometa® to her starting in April 2002. Stevens remained on Zometa® until March 2005, and suffered no skeletal-related events during that period.

In September of 2004, Stevens badly broke a tooth in her lower right jaw. (Tr. 300:1-11.) Her oral surgeon, Dr. Eugene Morris, removed the tooth on September 27. There was no alternative treatment option that did not involve dental surgery. (Tr. 326:22-327:9, 345:3-6.)

The Zometa® label in effect at the time of Stevens' September 2004 tooth extraction contained FDA-approved language expressly warning of the possibility of ONJ in Zometa® users undergoing a dental procedure:

> **Cases of osteonecrosis (primarily involving the jaws) have been reported in patients treated with bisphosphonates. The majority of the reported cases are in cancer patients attendant to a dental procedure.** Osteonecrosis of the jaw has multiple well documented

> risk factors including a diagnosis of cancer, concomitant therapies (e.g., chemotherapy, radiotherapy, corticosteroids) and co-morbid conditions (e.g., anemia, coagulopathies, infection, pre-existing oral disease). Although causality cannot be determined, **it is prudent to avoid dental surgery as recovery may be prolonged.**

(March 2004 Label, Pl.'s Ex. 190, Tr. 887:13-20 (emphasis added).)

2. Stevens' injury and her claims against her doctors.

Following the extraction of her broken tooth, Stevens developed a jaw condition. This condition was diagnosed by Dr. Morris as osteonecrosis of the jaw on March 18, 2005.

Stevens was informed by Dr. Schmidt of the alleged connection between Zometa® and her ONJ in early 2005. (Tr. 754:12-25.) Stevens, a registered nurse with decades of medical experience, performed her own research on Zometa® and ONJ in 2005, and learned – if she did not know it before – that Zometa® was an NPC drug. (Tr. 797:21-798:6 (Stevens testifying that she performed her own research in 2005 and from that research knew that Zometa® is an NPC drug).) She also saw during that research an NPC package insert. (*See* Pl.'s Resp. Def.'s Third Disc. Req. at 4 (listing articles gathered by Stevens in her research, including the 2004 Zometa® package insert) (cited discovery requests/responses attached as Exhibit 3 to NPC's Submission of Evidence Proffered at Trial and Refused).)

On August 31, 2007, Stevens brought an action against Drs. Schmidt and Morris before the Montana Medical-Legal Panel ("MMLP"), claiming that both of

them had failed to warn her of the risks of dental surgery while taking Zometa®. In his answer, Dr. Morris stated that the tooth extraction that Stevens received was "the only realistic treatment option" for her, and that he would have recommended it regardless of the risks of Zometa®. (Morris Answer 2 (Exhibit 1 to NPC's Submission of Evidence Proffered at Trial and Refused).)

On January 18, 2008, Stevens sued Dr. Schmidt and her medical practice, Guardian Oncology. She stated that Dr. Schmidt had failed to warn her of an increased risk of developing osteonecrosis of the jaw because she was being treated with Zometa®. (Compl. ¶ 16.) Stevens also sued "John Does 1 through 5". Stevens served discovery responses and filed expert disclosures of three experts who would have testified that Dr. Schmidt was adequately informed of the potential risk of ONJ in connection with dental procedures, and therefore had a duty to advise Stevens of the risk. (9/15/08 Pl.'s Expert Witness Disclosure at 2-3; 2/27/09 Pl.'s Expert Witness Disclosure at 8-9, 11-13.)

3. Stevens' claim against NPC.

On January 13, 2009, Stevens amended her complaint to add new defendants NPC and Patrick Doyle, one of NPC's sales representatives.[1] The claim against NPC was that NPC "did not, in a timely fashion, provide to Dr. Schmidt or

[1] The claim against the sales representative Doyle was later dismissed as being without legal foundation. (4/7/09 Order.)

Guardian Oncology all of the information about which [it was] aware which warned of osteonecrosis of the jaw as a potential complication from tooth extractions while being treated with Zometa®." (Am. Compl. ¶ 20.)

On or about June 12, Stevens settled her claim against Dr. Schmidt for a substantial sum. (*See* 1/20/10 Order at 12 (stating settlement amount).) Stevens then moved to amend her complaint to remove all claims against Dr. Schmidt and Guardian Oncology. This motion was denied. (9/14/09 Order.) On June 24, 2009, NPC served discovery on Stevens seeking disclosure of the amount of the settlement. Dr. Schmidt was dismissed from the case on July 8, and on July 23, Stevens responded to NPC's discovery request, refusing to disclose anything. Twelve days later, NPC moved to amend its answer to add an apportionment defense. The trial court denied NPC's motion to amend as untimely and refused to allow discovery of any settlement information until after the trial.

4. NPC's dispositive motions.

On February 26, 2009, NPC filed a motion to dismiss and/or for summary judgment because Stevens filed her amended complaint naming NPC long after the statute of limitations had expired. (*See* NPC's Mot. Dismiss and/or Summ. J. on Stat. of Limits. 7.) In her response, Stevens did not argue that her claims were timely filed within the three-year limitations period set forth in MCA § 27-2-204(1). Rather, she argued that her out-of-time claims against NPC related back to

the date of her original complaint under MCA § 25-5-103, Montana's "fictitious name" statute, which provides: "When plaintiff is ignorant of the name of the defendant, such defendant may be designated in any pleading or proceeding by any name; and when his true name is discovered, the pleadings or proceedings may be amended accordingly."[2] (Pl.'s Resp. Mot. Dismiss and/or Summ. J. on Stat. of Limits. 8-9.)

Stevens does not claim to have been ignorant of the identity of NPC prior to filing her original complaint; she concedes that "she knew that Zometa was manufactured by Novartis and that Zometa contributed to the cause of her osteonecrosis." *Id.* at 10. She also was aware of the facts constituting the claim against NPC prior to filing her original complaint; she admits that "she knew, prior to filing her Complaint that there was information available which explained the relationship [between Zometa use and ONJ in individuals undergoing tooth extraction] and that it had not been provided to her." *Id.*

What Stevens claims to have been "ignorant" of for purposes of the fictitious name statute is not the identity of NPC but the identity of sales representative Patrick Doyle, a separately-named defendant, or that he was an NPC employee. *Id.* (claiming that Stevens "did not know the name of the person responsible for

[2] On October 1, 2009 the fictitious name statute, like all Montana statutes, was amended to provide gender neutral language. The substance of the statute was not affected.

providing [information about Zometa and ONJ] to the doctor nor the name of the company which employed that person"). She also asserts that she was not aware of what information had been withheld from Dr. Schmidt and Guardian Oncology by NPC. (*See* Pl.'s Mem. Supp. Mot. File Second Am. Compl. 3.)

The trial court denied NPC's motion, holding that the statute of limitations was tolled because "the nature of Novartis' alleged culpability may have been unknown at the time of Plaintiff's original complaint." (4/7/09 Opinion & Order 5-6.)

On September 11, 2009, following the close of discovery, NPC filed a second motion for summary judgment on the statute of limitations based on additional evidence that plaintiff admits she had seen before she filed her original complaint – both NPC's package insert for Zometa® *and* a Dear Doctor letter issued after her injury which her attorney described at trial as "the first clear signal sent by Novartis to anybody that these extractions should be avoided." (Tr. 1675:17-19.) The trial court denied NPC's motion for the same reasons as before. (10/8/09 Opinion & Order.)

Standard of Review

The Court reviews a district court's conclusions of law *de novo* for correctness. *Hidden Hollow Ranch v. Fields*, 2004 MT 153, ¶ 21, 321 Mont. 505, 92 P.3d 1185; *Carbon County v. Union Reserve Coal Co.*, 271 Mont. 459, 469, 898 P.2d 680, 686 (1995). Evidentiary rulings are reviewed for abuse of discretion. *Sunburst Sch. Dist. No. 2 v. Texaco, Inc.*, 2007 MT 183, ¶ 74, 338 Mont. 259, 165 P.3d 1079. Jury instructions are reviewed to determine "whether, as a whole, they fully and fairly instruct a jury on the law applicable to the case." *Ammondson v. Northwestern Corp.*, 2009 MT 331, ¶ 38, 353 Mont. 28, 220 P.3d 1. When the jury instructions do not "correctly state[] the applicable law," resulting in prejudice, there is reversible error. *Walden v. State*, 250 Mont. 132, 137-38, 818 P.2d 1190, 1193 (1991).

Summary of the Argument

NPC is entitled to judgment as a matter of law because Stevens did not name NPC as a defendant within Montana's three-year statute of limitations. She attempts to excuse this by invoking the fictitious name statute. However, that statute applies only when a plaintiff "does not know the name of the defendant." Stevens admits she knew in 2005 that NPC manufactured Zometa®.

NPC is entitled to a new trial because the trial Court erroneously instructed the jury that NPC's duty to warn of the risks of its drug extended to non-prescribing treating physicians and even to non-physician caregivers like nurses. That instruction was contrary to Montana law, which provides that a pharmaceutical company's duty to warn extends only to the prescribing physician.

NPC is entitled to a new trial because it was unfairly prohibited from showing that it adequately warned the prescribing physician by the Court's erroneous exclusion of statements by Stevens in discovery responses, pleadings, and other filings that were inconsistent with NPC's liability. These were judicial admissions and non-hearsay admissions of a party-opponent. NPC also was unfairly prohibited from showing that it adequately warned the prescribing physician by the Court's refusal to permit it to amend its complaint to assert an apportionment defense once Stevens settled her lawsuit against the prescriber. NPC also was improperly barred from impeaching Stevens with the fact of the

settlement with the prescriber or even the fact that she had sued her physician on a theory inconsistent with the one she advanced against NPC.

NPC is entitled to judgment as a matter of law because Stevens failed to prove proximate causation. Her theory of her injury was that she was not adequately warned to avoid dental surgery while on Zometa®. The evidence, however, demonstrated that some form of dental surgery was necessary at that time due to a broken tooth, and thus no warning could have prevented the surgery. Since Stevens failed to establish that there was some less-invasive procedure that she could have gotten if she had been warned that would have reduced or eliminated her risk of developing ONJ, she failed to carry her burden of proof to establish a link between the alleged failure to warn and her injury. NPC also is entitled to a new trial because the Court excluded a statement in another matter made on behalf of the oral surgeon who extracted her tooth stating that extraction was the only option available to her.

Finally, NPC is entitled to a new trial because the Court erroneously admitted testimony regarding a change to the label for Zometa® that postdated Stevens' injury as proof that NPC should have given that warning earlier. A pharmaceutical label change is an inadmissible subsequent remedial measure.

Argument

I. Stevens' suit against NPC was filed more than three years after her injury and is thus barred by the statute of limitations.

A. Stevens did not sue NPC within the limitations period.

Stevens' claims against NPC should have been dismissed because they are barred by Montana's three-year statute of limitations, MCA § 27-2-204(1). Stevens first named NPC on January 13, 2009; it is entirely undisputed that she sued NPC almost four years after her physician diagnosed her with ONJ and notified her of an alleged causal connection between Zometa® and ONJ.

In Montana, the statute of limitations on a personal-injury claim begins to run when a plaintiff discovers the cause of her alleged injuries. *See Bennett v. Dow Chem. Co.*, 220 Mont. 117, 121, 713 P.2d 992, 995 (1986) (affirming dismissal of plaintiff's untimely claims and holding that plaintiff cannot "utiliz[e] discovery doctrine to toll the statute of limitations beyond discovery of the cause of an injury"). A doctor's diagnosis and observations on cause satisfy the "discovery" requirement under Montana law. *Id.* (holding that the statute of limitations for plaintiff's claims began to run when plaintiff's doctor diagnosed his injuries and informed him of the suspected cause); *Nelson v. Nelson*, 2002 MT 151, ¶ 26, 310 Mont. 329, 50 P.3d 139 (statute of limitations began to run when plaintiff's physician associated her alleged injuries with exposure to certain chemicals and accidental vaccine injection). The three-year statute of limitations on Stevens'

claim thus began to run in March of 2005 when Dr. Schmidt both diagnosed her with ONJ and attributed the cause to Zometa®. (*See* Tr. 754:12-25 (Stevens testifying that Dr. Schmidt told her in late 2004 or early 2005 that she may have ONJ due to Zometa®).) Stevens has conceded that her suit would be barred by the statute of limitations but for her interpretation of the fictitious name statute. (Tr. 1613:11-25 (Stevens' counsel acknowledging that judgment as a matter of law would be proper but for the fictitious name statute because "Peggy Stevens knew the manufacturer of the drug that she was taking within three years of March 18, 2005" and because "[o]f course she knew that Zometa was manufactured by Novartis and she knew that she had osteonecrosis").)

Because Stevens did not assert any claims against NPC until January of 2009 – ten months after the statute of limitations on her injuries had expired – her claims against NPC are time-barred and should have been dismissed.

B. The clear language of the fictitious name statute precludes Stevens' untimely claims because she knew the identity of NPC prior to filing her original lawsuit.

1. Montana law does not permit the statute of limitations to be tolled while a plaintiff discovers the existence of her cause of action.

Stevens argued before the trial court that her untimely failure to warn claim against NPC was excused by Montana's fictitious name statute. The fictitious

name statute establishes a procedure by which a plaintiff who "does not know the name" of a defendant when a complaint is filed may name them later:

> When the plaintiff **does not know the name of the defendant**, the defendant may be designated in any pleading or proceeding by any name. **When the defendant's true name is discovered**, the pleadings or proceedings may be amended accordingly.

MCA § 25-5-103.[3] In Montana, "It is well-established that when the language of a statute is clear and unambiguous, the statute speaks for itself. We will not 'insert what has been omitted ... or omit what has been inserted' nor will we resort to other means of interpretation." *Kulstad v. Maniaci*, 2009 MT 403, ¶ 10, 353 Mont. 467, 221 P.3d 127 (quoting MCA § 1-2-101); *see also JTL Group, Inc. v. New Outlook, LLP*, 2010 MT 1, ¶ 36, 355 Mont. 1, 223 P.3d 912 ("We interpret statutes according to their plain language; if the language of the statute is clear on its face, this Court looks no further.").

Stevens admits that she in fact knew NPC's name when the original complaint was filed. (*See, e.g.*, Pl.'s Resp. Mot. Dismiss and/or Summ. J. on Stat. of Limits. 9 ("[P]rior to filing her [original] complaint, [s]he also knew that the drug which caused her injury had been manufactured by [NPC]").) Her action against NPC is therefore timely only if the fictitious name statute can be

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[3] "Plaintiff's knowledge about the defendant's true name [is determined] at the time of the filing of the original complaint." *Molina v. Panco Const., Inc.*, 2004 MT 198, ¶ 8, 322 Mont. 268, 95 P.3d 687 (holding that "plaintiff's ignorance of defendant's true name must be genuine and not feigned.").

interpreted to permit a plaintiff to name a defendant late not only because she is ignorant of the defendant's *name*, but also because she claims to be ignorant of "the nature of the defendant's culpability." *See id.* at 12. Stevens argued, and the trial court evidently accepted, that discovery of "the name of the defendant" in the statute should be read to include discovery of "the cause of action against the defendant."

Stevens' proposed rewriting of the fictitious name statute, in addition to violating Montana's canons of statutory interpretation, flatly contradicts Montana limitations law, which has long been clear that the statute of limitations is *not* to be extended to the discovery of a cause of action as opposed to the physical cause of an injury. The Supreme Court has in the past been invited to adopt discovery of the cause of action as a trigger for the running of the statute of limitations, and has "expressly decline[d] to extend discovery doctrine to toll statutes of limitation until discovery of legal rights." *Bennett v. Dow Chem. Co.*, 220 Mont. 117, 122, 713 P.2d 992, 995 (1986). In *Bennett*, the Supreme Court was faced with a pesticide applicator's assertion that he should have been allowed to file suit more than three years after his injury because he did not discover his cause of action until later. The Court noted that the appellant "is asking us to apply a 'discovery rule' by which the statute of limitations was tolled until the appellant 'discovered' his legal rights." *Id.* at 120, 713 P.2d at 994. The Court refused to do so, *id.* at 122, 713

P.2d at 995, and noted that "the *farthest reaches of [the] discovery doctrine in Montana*" were represented by a case in which the limitations period was tolled "until the plaintiff discovered that his [injury] may have been caused by the drug." *Id.* at 121, 713 P.2d at 995 (emphasis added); *see also Sternhagen v. Dow Co.*, 711 F. Supp. 1027, 1030 (D. Mont. 1989) (recognizing that Montana law does *not* permit a plaintiff to toll the statute of limitations until she discovers her legal rights). This is in accordance with Montana statutory law as well. MCA § 27-2-102(2) ("Lack of knowledge of the claim or cause of action, or of its accrual, by the party to whom it has accrued does not postpone the beginning of the period of limitation.").

Stevens' interpretation of the fictitious name statute amounts to an assertion that a statute of limitations that *could not be tolled* under controlling law under other circumstances *can* be tolled under the guise of the fictitious name statute simply by naming a "John Doe" defendant whose identity is known to the plaintiff when the original lawsuit is filed. This interpretation violates both Montana's rules of statutory interpretation and the clear authority of Montana limitations law.

2. Montana law does not permit the statute of limitations to be tolled by the fictitious name statute when a plaintiff is aware of the identity of the defendant.

Even if it were legally permissible to invoke the fictitious name statute to justify a suit timed to the discovery of the cause of an injury, which it is not, the

tactic would be unavailable here, since no plausible case can be made that Stevens was ignorant of the facts that constituted her claim against NPC. *See Carl v. Chilcote*, 255 Mont. 526, 532 844 P.2d 79, 83 (1992) (statute of limitations begins to run when plaintiff is aware of "the facts constituting the claim ... notwithstanding the fact that [the plaintiffs] may not have realized they had a possible claim against the City").

In this case, Stevens knew, before filing the original complaint against Dr. Schmidt and long before suing NPC:

- Zometa® was an NPC drug;[4]
- Zometa® allegedly caused ONJ in people undergoing invasive dental procedures;[5]
- There was information about the causal connection that she believed had not been provided to her prior to her tooth extraction;[6]
- The contents of NPC's package insert for Zometa® prior to her extraction and injury;[7]

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[4] (Tr. 797:21-798:6 (Stevens testifying that she performed her own research in 2005 and from that research knew that Zometa® is an NPC drug).)

[5] (*See* Pl.'s Resp. Def.'s Third Disc. Req. 4 (listing articles gathered by Stevens in her literature search, including a September 2003 article by Dr. Robert Marx discussing the alleged association between tooth extractions and ONJ in Zometa patients).)

[6] Stevens admitted that she "knew prior to filing her Complaint that there was information available which explained the relationship [between Zometa® use and ONJ in individuals undergoing tooth extraction] and that it had not been provided to her." (Pl.'s Resp. Mot. Dismiss and/or Summ. J. on Stat. of Limits. 10.)

[7] Stevens' *pre-filing* research revealed not only a Zometa® package insert, but the September 24, 2004 Dear Doctor letter as well. (*See* Pl.'s Resp. Def.'s Third Disc. Req. 4 (listing articles

- The contents of a Dear Doctor letter sent out after her injury, warning doctors of the risks of ONJ, which Stevens' attorney described at trial as "the first clear signal sent by Novartis to anybody that these extractions should be avoided."[8]

Indeed, it was based on this information that Stevens filed suit in January 2008 against Dr. Schmidt for failing to warn her of the risks of Zometa® – precisely the same claim that she later asserted against NPC. (*Compare* Compl. ¶¶ 16-18 *with* Am. Compl. ¶¶ 14-20.)

Montana law does not permit the fictitious name statute to be used to escape the ordinary operation of the statute of limitations under such circumstances. In *Franchi v. City of Helena*, No. BDV-04-262, 2005 Mont. Dist. LEXIS 529, at *5-6 (Mont. Dist. Ct. Mar. 16, 2005), for example, the court rejected application of the fictitious name statute and granted summary judgment based on the statute of limitations because plaintiff "[did] not even suggest that they were ignorant of the name of the Defendant," but rather "claim[ed] that they were ignorant of facts giving rise to the [defendant's] liability." The plaintiff, who was injured riding his bicycle in Helena, originally named several defendants, including several "John Does", but not the City of Helena. After the statute of limitations had run, plaintiff attempted to substitute the City of Helena for a John Doe defendant. The plaintiff

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gathered by Stevens in her literature search, including the Dear Doctor letter which also enclosed a copy of the 2004 Zometa® package insert).)

[8] (*See id.* (Dear Doctor letter); Tr. 1675:17-19 (Stevens' attorney's comments).)

knew the name of the defendant, but claimed to be unaware that the other defendants would blame the City for failing to enforce an ordinance. *Id.* The court correctly found that the fictitious name statute was "very clear," and held "[t]his Court will not rewrite the statute." *Id.*

Similarly, in *Dover v. Sadowinski*, 194 Cal. Rptr. 866 (Cal. Ct. App. 1983), plaintiff argued that the defendants negligently caused the death of his wife. After the statute of limitations expired, plaintiff attempted to substitute the defendant physician for a "John Doe" defendant. *Id.* at 867. The court found dismissal proper, noting that the plaintiff's attorneys had admitted that they were aware of defendant's identity but – as Stevens' attorneys did here – argued that they simply did not know how "deeply" the defendant was involved. *Id.* at 869. The court rejected plaintiff's attempt "to create a new standard to be applied in the application of [the fictitious name statute that] ... the plaintiff must be aware of each and every detail concerning that person's involvement." *Id.*[9]

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[9] *See also Gordon v. Kawamoto*, No. B211948, 2010 WL 1408986, at *9 (Cal. Ct. App. Apr. 9, 2010) (amended complaint naming Doe defendants did not relate back to filing of original complaint because plaintiff should have known the identities of substituted defendants at the time he filed his original complaint; defendants' names were in his medical records and plaintiff knew he had been treated at defendants' hospital); *Lomas v. Dragosz*, No. D054831, 2010 WL 629495, at *5 (Cal. Ct. App. Feb. 24, 2010) (affirming summary judgment because plaintiff knew identity of Doe defendant at time she filed original complaint where plaintiff had previously read traffic accident information card that included Doe defendant's name); *Carey v. Hackensack Univ. Med. Ctr.*, 2009 WL 4547211, at *5 (N.J. Super. Ct. App. Div. Dec. 3, 2009) (plaintiff who was aware of defendant's identity could not use fictitious name statute to avoid limitations period, despite plaintiff's contentions that he was unaware of a potential theory of liability against defendant until after limitations period had expired); *Powell v. Coffee Beanery,*

Under Montana law, mere knowledge of NPC's identity, without more, would be sufficient to render Montana's fictitious name statute unavailable as an excuse for her late filing. Here, however, Stevens and her attorney knew far more. Based on her own pre-suit research, Stevens believed that she had been inadequately warned, and sued Dr. Schmidt for it. In her research she learned not only that NPC made Zometa®, but also obtained the NPC warnings in effect prior to her injury and a Dear Doctor letter sent out after her injury, which her lawyer called at trial "the first clear signal sent by Novartis to anybody that these [dental] extractions [in patients on Zometa®] should be avoided." (Tr. 1675:17-19.) Stevens provided these to her lawyer. There is no precedent in Montana for any plaintiff with such knowledge claiming – under any legal pretext, including the fictitious name statute – that her ignorance permitted her to file suit without timely naming a defendant known to her. If the decision of the trial court in this case is not overturned, any plaintiff who simply names a John Doe in her initial complaint will be able to argue that she may add defendants for years and years after the expiration of the statute of limitations because she belatedly learned "the nature of

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Ltd., 965 F. Supp. 971, 975-76 (E.D. Mich. 1997) (rejecting plaintiff's argument that he was ignorant of "the name" of the defendants within the meaning of California's fictitious name statute since he did not understand that the facts would give rise to a claim); *Miller v. Thomas*, 175 Cal. Rptr. 327 (Cal. Ct. App. 1981) (rejecting fictitious name argument for tolling of limitations where plaintiffs' attorney was aware of the identity of the late-named defendant, and holding that a person who is knowingly omitted from a complaint may not be joined as a fictitiously named party after the statute of limitations has run).

the defendant's culpability."[10] The decision must not be allowed to stand, and judgment should be entered in favor of NPC as a matter of law.

3. Stevens' claimed ignorance of the identity of an NPC sales representative who was later dismissed with prejudice has no bearing on the untimeliness of her action against NPC.

At the same time that she named NPC as a defendant, Stevens also named NPC sales representative Patrick Doyle. Doyle moved for dismissal of this claim, which was independent of the claim against NPC, and the trial court properly granted the motion on the ground that no claim could be asserted against him.[11] Stevens has tried to bootstrap her claim that she was ignorant of the identity of *NPC* by claiming that she was ignorant of the identity of one of NPC's agents, Doyle.

Stevens' knowledge of Doyle is irrelevant. Under Montana law, a plaintiff has a cause of action against all entities in the chain of distribution of an allegedly defective product, including retailers and distributors as well as manufacturers such as NPC. *See Durden v. Hydro Flame Corp.*, 1999 MT 186, ¶ 19, 295 Mont. 318, 983 P.2d 943. As such, regardless of whether Doyle was or was not employed by

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[10] Here, Stevens has argued that she did not know about the extent of NPC's misconduct underlying her cause of action until "mid-July [2009]," *after* suing NPC and gaining access to "literally hundreds of thousands of pages of documents." (*See* Pl.'s Reply Supp. Mot. File Second Am. Compl. 7; *see also* Tr. 827:23-828:2 (Stevens testifying that she did not know "the *extent* of Novartis's knowledge" prior to filing her suit against Novartis).) There is no limit to the exception that Stevens would create within Montana limitations law.

[11] (4/7/09 Opinion & Order at 6-8 (dismissing claim against Doyle for fraudulent joinder).)

NPC, NPC's liability as the manufacturer of the product at issue would be independent – exactly as Stevens alleged and litigated in this case.

C. In the alternative, NPC is entitled to a new trial because the trial court refused even to instruct the jury on NPC's limitations defense.

Compounding its legal error, the trial court refused *both sides'* proposed jury instructions and verdict form questions regarding the statute of limitations, Pl.'s Proposed Instr. No. 40-42, NPC's Proposed Instr. No. 1-3, and NPC's Proposed Verdict Form, thus erroneously resolving as a matter of law the question of whether Stevens had timely sued NPC. (Tr. 1611:6-1614:8.) Even if Stevens' novel assertion that the statute had been tolled until she discovered her cause of action against NPC were correct, limitations is a jury question "when there is conflicting evidence as to when the cause of action accrued." *Hill v. Squibb & Sons, E.R.*, 181 Mont. 199, 212, 592 P.2d 1383, 1390-91(1979). The trial court previously held that a "genuine issue of material fact" precluded summary judgment on the statute of limitations. (*See* 10/8/09 Order 6.) Contrary to its holding and despite the record in this case,[12] the trial court then took the issue away from the jury, which entitles NPC to a new trial, if judgment is not entered.

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[12] (*See* Tr. 827:23-828:2 (Stevens testifying that she had no understanding of her claim prior to the time of her lawsuit against NPC); *but see supra* pp. 19-20 (establishing that Stevens was aware at the time of the original complaint against Dr. Schmidt of all facts necessary to state a claim against NPC); Tr. 1313:8-1315:5, 1325:11-1330:11 (NPC's FDA expert Dr. Arrowsmith testifying regarding NPC's ONJ warnings prior to Stevens' dental surgery).)

II. NPC is entitled to a new trial because the trial court's rulings made it impossible to demonstrate that NPC fulfilled its duty to warn.

A. The trial court erroneously instructed the jury that NPC had a duty to warn healthcare providers other than Dr. Schmidt, the physician who prescribed Zometa® to Stevens.

Montana follows the learned intermediary doctrine, which provides that "the duty of a drug manufacturer to warn of the dangers inherent in a prescription drug is satisfied if adequate warning is given *to the physician who prescribes it.*" *Hill v. Squibb & Sons, E. R.*, 181 Mont. 199, 206, 592 P.2d 1383, 1387-88 (1979) (emphasis added). Nevertheless, the trial court instructed the jury over NPC's objection that NPC was required to provide adequate warnings not only to the prescribing physician but also to "*treating healthcare providers who are in a position to reduce the risks of harm ... and other healthcare providers who are in a position to reduce the risks of harm.*" (Jury Instr. No. 13 (emphasis added); Tr. 1656:2-11; Tr. 1599:11-1600:23 (NPC's objection).) The trial court further wrongly instructed the jury that causation could be satisfied with evidence that "a sufficient warning *would have ... prompted [Stevens'] medical providers to take precautions to avoid the injuries that she suffered.*" (Tr. 1656:14-20 (emphasis added); Tr. 1602:4-25 (NPC's objection).) The trial court rejected NPC's proposed instructions that correctly stated that its duty was to provide an adequate warning *to the treating physician*, Dr. Schmidt. (*See* Tr. 1621:10-23, 1622:6-14 (NPC's offer and trial court's refusal of instructions).)

The language of Stevens' instruction was taken from the Restatement (Third) of Torts § 6(d), *see* Pl.'s Proposed Instr. No. 15, which Stevens' counsel represented to the trial court as the law in Montana. (*See* Tr. 1598:23-25, 1599:12-14.) In fact, § 6(d) has never been adopted in Montana, and the only sections of the Restatement (Third) that *have* been considered have been rejected. *See Malcolm v. Evenflo Co., Inc.*, 2009 MT 285, ¶¶ 34-40, 352 Mont. 325, 217 P.3d 514 (rejecting § 4); *Sternhagen v. Dow Co.*, 282 Mont. 168, 182, 935 P.2d 1139, 1147 (1997) (rejecting § 2).

1. Under Montana law, a drug manufacturer's duty to warn extends only to the prescribing physician.

The law of Montana is not § 6(d), but the learned intermediary doctrine, which provides that, since the *prescribing physician* is in the best position to assess the risks and benefits of a particular course of treatment, a drug company's duty to warn is discharged by providing an adequate warning to her. *See* Beck & Vale, Drug and Medical Device Product Liability Deskbook § 2.03[1]; *In re Fosamax Prods. Liab. Litig.*, No. 1:06-MD-1789-JFK, 2010 WL 330220, at *5 (S.D.N.Y. Jan. 27, 2010) (in pharmaceutical case involving purported ONJ, holding that "the duty to warn runs from the drug manufacturer to the treating physician – not the patient. The causation inquiry therefore focuses on the hypothetical actions of Plaintiff's treating physician had he been provided a proper warning.") (internal citations omitted). The trial testimony of Stevens' regulatory expert Dr. Parisian

explained the reasoning for the doctrine: the manufacturer's warnings enable the prescribing physician to perform a risk-benefit analysis about her use of the drug. (*See* Tr. 926:25-927:12.) The learned intermediary doctrine comes from the famous comment k to Section 402A of the Restatement (Second) of Torts, which has – unlike the Restatement (Third) – been very widely embraced, including in Montana. *See Brandenburger v. Toyota Motor Sales*, 162 Mont. 506, 512-15, 513 P.2d 268, 272-74 (1973) (adopting section 402A); *Jones v. Aero-Chem Corp.*, 680 F. Supp. 338, 339 (D. Mont. 1987) (noting that "the State of Montana has unequivocally adopted section 402A of the Restatement of Torts").

The Montana case adopting the learned intermediary doctrine is *Hill v. Squibb & Sons, E. R.*, in which the Supreme Court held that "the duty of a drug manufacturer to warn of the dangers inherent in a prescription drug is satisfied if adequate warning is given *to the physician who prescribes it.*" 181 Mont. 199, 206, 592 P.2d 1383, 1387-88 (1979) (emphasis added). In *Hill*, the Court made clear that its holding is a "logical extension" of the learned intermediary doctrine "since the warning is directed to physicians." *Id.* at 206, 592 P.2d at 1388. As in this case, "[t]he central theory of the claim was that ... the package inserts provided with the drug did not warn specifically enough of its dangerous side effects." *Id.* at 203, 592 P.2d at 1386; *see* 10/6/09 Pretrial Order 2 (Stevens claiming that NPC failed to adequately warn "about the risks associated with

Zometa use"). *Hill* has been recognized by authorities nationwide as adopting the learned intermediary doctrine in Montana, and NPC knows of *no* authority adopting plaintiff's view of Montana law.[13]

2. The trial court erred by instructing the jury that NPC had a duty to warn treating healthcare providers other than the prescribing physician.

By incorrectly casting NPC's duty in § 6(d)'s terms of "treating healthcare providers" rather than in terms of the prescribing physician as required by *Hill*, the trial court erroneously directed the jury to consider whether NPC adequately warned non-oncology healthcare providers, such as Stevens' oral surgeon, Dr. Morris, as well as various visiting physicians at Guardian Oncology, in addition to the prescribing oncologist Dr. Schmidt. Stevens' counsel aggressively took advantage of the legal error, arguing in closing that the jury should apply the improper instruction, *see* Tr. 1804:9-13, and find NPC liable for failing to warn the non-prescribers, *see* Tr. 1674:10-1675:5, 1807:18-1808:3. Stevens' counsel had elicited testimony that the oral surgeon Dr. Morris was not aware of the oncologist-directed warnings at the time of Stevens' tooth extraction, Tr. 302:22-303:1, thus enabling the jury to find a breach of the "duty" that was wrongly identified in the instruction. In light of the improper instruction, NPC is entitled to a new trial. *Cf. Hall v. Big Sky Lumber & Supply, Inc.*, 261 Mont. 328, 334, 863 P.2d 389, 393

[13] *See* cases and authorities assembled in the Supplemental Appendix.

(1993) ("[B]ecause the trial court presented an instruction on a key issue of law which was incorrect as a matter of law, a reversal is required.").

3. The trial court erred by instructing the jury that NPC had a duty to warn non-physicians.

Stevens' counsel also took advantage of the trial court's erroneous instruction that NPC's duty extended to "treating healthcare providers" to argue that NPC should be held liable for failing to provide warnings to treating *nurses*. (*See, e.g.*, Tr. 1674:10-1675:5 (urging the jury to find NPC liable for failure to warn nurses, particularly Joni Landes); Tr. 1807:18-1808:3 (arguing that causation is satisfied by testimony that Landes and other nurses were not warned); Tr. 1674:10-11 ("when it gets down to it, what difference does [the adequacy of the warning to prescriber Dr. Schmidt] make?").) Again, the trial court's erroneous instruction enabled the jury to find that NPC breached a duty based on otherwise legally insignificant testimony – for example, that nurse Landes was not aware of the warnings, Tr. 1031:3-10. In light of the incorrect instruction, NPC is entitled to a new trial.[14]

[14] "[N]urses generally are not capable of providing the degree of individualized medical judgment rendered by physicians and are not authorized independently to prescribe drugs, and as such, the learned-intermediary rule does not extend to them. Although nurses often perform tasks similar to those performed by physicians ..., these tasks are typically performed under the supervision of, or in collaboration with, physicians; at bottom it is the physician who is ... ultimately held accountable for that decision." 63A Am. Jur. 2d Prods. Liab. § 1207; Am. L. Prod. Liab. 3d § 33:41.

B. The trial court erred by excluding all evidence of statements and admissions made by Stevens against Dr. Schmidt.

In her original complaint, and in her Amended Complaint in which she added NPC as a party, in her expert disclosures, and in her discovery responses to Dr. Schmidt, Stevens stated that Dr. Schmidt was actually aware – as she said any reasonable oncologist would be by September 27, 2004 – of the risks of dental surgery in a patient on Zometa®.[15] After settling with Dr. Schmidt, Stevens sought to amend her complaint, deleting her statements regarding Dr. Schmidt. The trial court denied that motion, but nevertheless precluded NPC from introducing or referring to any of Stevens' statements about Dr. Schmidt. The trial court found the statements were not judicial admissions or party admissions. (10/13/09 Order Regarding Prior Pleadings 2-3.) The trial court also incorrectly held that such documents could be used at trial only if they had been signed by Stevens rather than her lawyers. (Tr. 728:13-729:5.)[16]

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[15] (*See* Compl. ¶¶ 12, 18; 2/27/09 Pl.'s Expert Witness Disclosure 2-4, 8-9, 11-13; Pl.'s Resp. Def.'s First Disc. Req. 16-17; NPC's Mot. In Limine to Permit Novartis to Introduce Prior Pleadings Asserting an Inconsistent Theory of Liability 7-8; 10/6/09 Pretrial Order 9-10.)

[16] The trial court wrongly prevented NPC from introducing evidence of even *the fact of the lawsuit* against Dr. Schmidt and Guardian Oncology, thus denying NPC its right to establish witness bias. (*See* Tr. 1018:1-6 (sustaining objection to question to Stevens seeking to establish the fact of the lawsuit).)

1. Stevens' pleadings, expert disclosures, and discovery responses made in her lawsuit against Dr. Schmidt were judicial admissions and statements that are not hearsay.

Stevens' pleadings are judicial admissions, i.e. "an express waiver made in court by a party or its counsel conceding the truth of an alleged fact." *Bitterroot Int'l Sys, Ltd. v. W. Star Trucks, Inc.*, 2007 MT 48, ¶ 41, 336 Mont. 145, 153 P.3d 627. Such admissions can be made at any point, including during "discovery [and] pleadings." *Kohne v. Yost*, 250 Mont. 109, 112, 818 P.2d 360, 362 (1991); *see Bitterroot*, 336 Mont. at 155-56 (statements in motions brief were judicial admissions). Allegations made in a pleading are "conclusive as against the pleader, and ... admissible as against the party making them in the litigation as proof of the facts which they admit." *Meadow Lake Estates Homeowners Ass'n v. Shoemaker*, 2008 MT 41, ¶ 45, 341 Mont. 345, 178 P.3d 81. It is the rule in Montana "that parties are bound by and estopped to controvert admissions in their pleadings." *Rowland v. Klies*, 223 Mont. 360, 368, 726 P.2d 310, 316 (1986). Even after amendment, a party's original pleading is admissible when it takes a position "inconsistent with the position taken in the amended complaint." *McDonald v. Peters*, 128 Mont. 241, 249, 272 P.2d 730, 734 (1954). An opposing party may introduce inconsistent pleadings "for whatever the jury might find it worth in arriving at the truth of the controversy." *Fox v. Fifth West, Inc.*, 153 Mont. 95, 100, 454 P.2d 612, 615 (1969).

Stevens' statements also are admissible under Mont. R. Evid. 801(d)(2), i.e., as statements of a party offered against a party. *See C. Haydon Ltd. v. Montana Mining Props., Inc.*, 286 Mont. 138, 148-49, 951 P.2d 46, 52-53 (Mont. 1997) (portions of transcript from another trial which included statements made by the party and the party's attorney were admissible as admissions by a party-opponent when offered against the party); *Heltborg v. Modern Mach.*, 244 Mont. 24, 39, 795 P.2d 954, 963 (Mont. 1990) (letter written by party admissible under Rule 801(d)(2) as admissions of party opponent).[17]

2. The trial court's exclusion of Stevens' pleadings, expert disclosures, and discovery responses because they were not signed by Stevens was erroneous.

The trial court's exclusion of pleadings and statements because they were not signed by Stevens herself was erroneous. *See Meadow Lake*, ¶ 45 ("[Statements] in a pleading are conclusive as against the pleader, and are admissible as against the party making them in the litigation."). Attorney statements are binding on parties in Montana. *Kohne*, 250 Mont. at 112 (attorney's "sayings and doings in the presence of the court concerning the trial of the cause are the same as though said and done by the party himself."); *Rasmussen v. Heebs Food Ctr.*, 270 Mont. 492, 496, 893 P.2d 337, 339-40 (1995) (counsel's positions

[17] Stevens' statements also were admissible as Rule 613(b) impeachment and as 804(b)(3) statements against interest.

bind the client); *Hill v. Merrimac Cattle Co., Inc.*, 211 Mont. 479, 504, 687 P.2d 59, 72-73 (1984) (attorney's statements in letter to client were non-hearsay under Rule 801(2)(d) because attorney was acting as client's agent concerning matter within scope of agency); *see also Williams v. Union Carbide Corp.*, 790 F2d 552, 555-56 (6th Cir. 1986) (attorney's statements in previous personal injury complaint alleging the cause was X were non-hearsay and admissible as substantive evidence in subsequent case in which party alleged the cause was Y); *Swahn Group, Inc. v. Segal*, No. C056970, 2010 WL 1347700, at *10 (Cal. Ct. App. Apr. 7, 2010) (allegations in a pleading verified by counsel are admissible against the party in other actions as party admissions even if not verified by the party).

C. The trial court erred by denying NPC's motion to amend its answer to assert an apportionment defense after Dr. Schmidt settled.

Dr. Schmidt was dismissed from the case on July 8, 2009, and Stevens responded to NPC's discovery request seeking information about the settlement terms on July 23. (*See* Pl.'s Resp. NPC's Third Disc. Req. (refusing to provide any information).) Just twelve days later, NPC moved to amend its answer to assert an apportionment defense under MCA § 27-1-703. (NPC's Mot. Am. Answer to Add Settled Defs.) The trial court denied the motion on the basis that NPC did not act with "reasonable promptness." (*See* 9/16/09 Order at 6; 10/9/09 Hr'g Tr. 6:5-13.) The trial court's holding under MCA § 27-1-703 was erroneous and caused NPC

irreparable harm in presenting its case to the jury by preventing it from making the case for the liability of Dr. Schmidt – as plaintiff had originally herself contended. *See* Mont. R. Civ. P. 15(a) (leave to amend "shall be freely given when justice so requires").

III. NPC is entitled to judgment as a matter of law because Stevens failed to present evidence establishing proximate causation and is entitled to a new trial because the trial court improperly excluded material evidence proving that Stevens' injury was not caused by a failure to warn.

A. NPC is entitled to judgment as a matter of law because Stevens failed to present evidence that NPC's alleged failure to warn caused the injury.

The trial evidence showed, and Stevens did not introduce evidence to dispute, that Stevens' fracture of her tooth made dental surgery *unavoidable* in September 2004 – that is, even had she been warned, she still would have had to have the dental surgery that she says triggered her ONJ. (*See* Tr. 320:13-14 (Dr. Morris testifying that Stevens' tooth was "split in half exposing some of the root"); Tr. 343:6-14, 327:17-328:22 (option of root canal was possible only in conjunction with crown lengthening, which is an invasive dental procedure involving removal of jawbone); Tr. 345:3-6 ("Q: Sir, you had no options for the treatment of tooth No. 31 that did not involve an invasive dental procedure; isn't that true? A: That's true.").) Because NPC's allegedly inadequate warning did not proximately cause the outcome about which plaintiff complains, judgment must be entered for NPC. *See Hoffmann-La Roche Inc. v. Mason*, 27 So. 3d 75, 77-78 (Fla. Dist. Ct. App.

2009) (reversing trial court because any inadequacies in drug's warning label could not have been proximate cause of plaintiff's injury where record established that different warning would not have altered treating physician's decision).

To the extent Stevens has contended she could have had a *less* invasive procedure than extraction, *see* Tr. 328:8-17, 327:22-24, she did not introduce any testimony or evidence that this would have prevented her from developing ONJ, or even that it would have reduced her risk. This is an essential link in the causal chain. *Riley v. Am. Honda Motor Co., Inc.*, 259 Mont. 128, 135, 856 P.2d 196, 200 (1993) (the Supreme Court has "consistently ... required a Plaintiff to establish a causal link between the lack of a warning and the accident and injuries in a failure to warn claim"). Whether dental surgery in the form of a dental extraction poses more risk of ONJ than dental surgery in the form of a crown lengthening is a medical question that exceeds common knowledge, so expert testimony was necessary on that point. *Hinkle v. Shepherd Sch. Dist. No. 37*, 2004 MT 175, ¶ 35, 322 Mont. 80, 93 P.3d 1239 (expert testimony is required where "the issue presented [causation of PTSD and other injuries] is sufficiently beyond the common experience of the trier of fact."). Stevens introduced no such expert testimony (or any other testimony) on this issue and therefore NPC should have been granted judgment as a matter of law. (*See* Tr. 1464:4-1465:1 (Rule 50 motion on proximate cause and denial).)

B. In the alternative, NPC is entitled to a new trial because the trial court erroneously excluded evidence showing that a different warning would not have prevented Stevens' injury.

It was crucial to Stevens' warnings causation case to prove that, had Dr. Schmidt received a different warning from NPC prior to Stevens' September 27, 2004 tooth extraction, Stevens would have avoided dental surgery and as a result would not have contracted ONJ. On this point, Stevens offered her own testimony and the testimony of the oral surgeon who extracted her tooth. (*See, e.g.*, Tr. 300:18-302:13 (Dr. Morris testifying that tooth extraction was not the sole surgical option); Tr. 260:18-22 (Stevens testifying that, had she known of risks, she would have opted not to have her tooth extracted).) NPC was erroneously barred from impeaching both witnesses with their written statements to the contrary, on the ground that neither statement was signed by the witness. (Tr. 310:15-315:20 (Court's rejection of MMLP evidence because not signed by Dr. Morris); Tr. 728:13-729:5 (Court's rejection of interrogatory responses because not signed by Stevens).)

1. The trial court erred by excluding Dr. Morris' statement from Stevens' MMLP claim against him, which established that the dental surgery that Stevens says triggered her injury was inevitable regardless of warnings.

NPC sought to introduce Dr. Morris' statement made in his answer before the Montana Medical-Legal Panel to the complaint filed against him by Stevens, in which he said that "Extraction of tooth #31 on September 27, 2004, was the only

realistic treatment option that would have been recommended for Stevens to elect even if it had been known she had been treated with Zometa and there may have been a potentially higher risk of osteonecrosis." (Morris Answer 2.)[18]

The MMLP statement is critical evidence, because if Stevens had to have her tooth extracted regardless of any risk of ONJ then no failure to warn of the risk of dental surgery could have caused her injuries. It is admissible as extrinsic evidence of a prior inconsistent statement by a witness. Mont. R. Evid. 613(b). The Supreme Court has recognized that impeachment of a witness at trial with prior statements is so important that denial of a litigant's right to cross-examine a witness with MMLP statements would deny them a "full and fair hearing" at trial. *See Linder v. Smith*, 193 Mont. 20, 30, 629 P.2d 1187, 1192 (1981) (expressly holding that a party has a right to use MMLP statements for impeachment at trial, stating that it is "fundamental to our adversarial system that litigants retain the right to impeach the sworn testimony of a witness testifying against them," and holding that a statutory provision barring the use of MMLP statements to impeach a witness was therefore unconstitutional).

[18] The MMLP documents were produced to NPC at deposition without objection from plaintiff's counsel. (Tr. 310:16-315:20.)

2. The trial court erred by excluding Stevens' interrogatory answers which state that prescriber Dr. Schmidt knew of the risk of ONJ being triggered by dental surgery in patients on Zometa®.

The trial court precluded NPC from cross-examining Stevens with her statements made in her interrogatory answers, in particular the statement that *Dr. Schmidt* was aware of the risk that ONJ could be triggered by dental surgery in patients on Zometa® but failed to tell Stevens of that risk. (*See* Tr. 728:13-729:5, 805:4-811:6, 1466:7-1467:4; Pl.'s Resp. Def.'s First Disc. Req. 16-17.) The statements tended to disprove Stevens' theory that NPC's failure to warn was the proximate cause of her injury, and as set forth in Section II.B.2, Stevens' interrogatory answers should have gone to the jury room because they are admissible both as non-hearsay statements of a party (Rule 801(d)(2)) and as impeachment of a witness (Rule 613(b)).

IV. NPC is entitled to a new trial because the trial court erroneously allowed Stevens to use NPC's warnings issued after her dental surgery to prove what warning NPC should allegedly have given before the surgery.

The trial court wrongly denied NPC's *in limine* motion and permitted Stevens to present inadmissible evidence of warnings given to Dr. Schmidt after the tooth extraction to prove what warning NPC should have given *before* the extraction. *See* Mont. R. Evid. 407 ("evidence of the subsequent measures is *not admissible to prove negligence ... or a need for a warning instruction*"); NPC's Mot. In Limine Excl. Corp. Actions 3; NPC's Reply Supp. Mot. In Limine Excl.

Corp. Actions 7-10; NPC's Mem. Excl. Landes Testimony 2; NPC's Reply Pl.'s Opp. NPC's Landes Mem. 2-5.

Nurse Landes testified that NPC's labeling changed in February 2005 to give "a positive link" between Zometa® and ONJ. (*See* Tr. 1033:14-21 ("Q: Based on what you went back and looked at, did you feel that the information in that package insert provided you any conclusive information about a relationship between Zometa and osteonecrosis of the jaw? A: Conclusive? No. They still weren't giving a positive link to that *until February 2005*.") (emphasis added); *see also* Tr. 1034:2-3 ("Those warnings sort of increased when I looked back in retrospect.").) In closing statements, Stevens' counsel used Landes' testimony concerning the post-extraction label change as proof that NPC's prior warnings were not adequate:

> We know that [Dr. Schmidt] would have done something differently [in September 2004] because as of February 2005 when they got the ... [2005 label change warning], which is the first clear notice that they had of the risk from a tooth extraction, they changed their whole office procedure. That's the simple fact. They not only would have done something differently, they have done something differently, and what they did differently, as we've just shown based on the facts, would have avoided what happened to Peggy Stevens.

(Tr. 1807:18-1808:3.)

A pharmaceutical manufacturer's change to a warning label is the quintessential inadmissible remedial measure.[19] The trial court committed reversible error when it denied NPC's *in limine* motion; Stevens should not have been allowed to present evidence regarding NPC's post-extraction warnings and the effect they had on the policies and procedures followed by Guardian Oncology.

Conclusion

For the reasons set forth above, NPC seeks reversal and entry of judgment in its favor or, in the alternative, a new trial.

DATED this 6th day of May 2010.

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[19] *See, e.g.*, *Gray v. Hoffman-La Roche, Inc.*, 82 F. App'x 639, 646 (10th Cir. 2003) (exclusion of label change was proper under Rule 407); *In re Propulsid Prods. Liab. Litig.*, No. MDL 1355, 2003 WL 1090235, at *1-2 (E.D. La. Mar. 11, 2003) (excluding under Rule 407 evidence of post-injury label changes).

CERTIFICATE OF COMPLIANCE

Pursuant to Rule 11(4) of the Montana Rules of Appellate Procedure, I certify that Appellant's Brief is printed in a proportionally spaced Times New Roman text typeface of 14 points; is double spaced; and word count calculated by Word 2007 is 9,768 words, excluding the Table of Contents, the Table of Authorities, the Certificate of Service, and this Certificate of Compliance.

DATED this 6th day of May 2010.

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I certify that on May 6th, 2010, I served a copy of the preceding document on the following:

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